SAUFLON PHARMACEUTICALS LIMITED

DEC 2 6 2001

K013649

510(k) Summary

SUBMITTER INFORMATION:

Company Name:	Sauflon Pharmaceuticals Ltd.
Address:	49 – 53 York Street Twickenham Middlesex TW1 3LP
Phone:	020 8322 4200
Fax:	020 8891 3001
Contact Person:	Dr Ligia Delacruz

DATE SUMMARY PREPARED: 31st October 2001

DEVICE NAME:

Trade Name:	SAUFLON 55 UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear
Common Name:	Contact Lens
Classification:	CLASS II (21 CFR 886.5925) SOFT (HYDROPHILIC) CONTACT LENS

SUBSTANTIAL EQUIVALENCE:

SAUFLON 55 UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear are substantially equivalent to FREQUENCY 55 (methafilcon A) Hydrophilic Contact lenses for Daily Wear (clear and tinted) that received market clearance pursuant to K973063, currently marketed in the USA.

DESCRIPTION of the DEVICE:

The **SAUFLON 55UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lenses for Daily Wear** is available as a single vision lens in an aquamarine visibility tint. The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid, which is cross-linked with ethyleneglycol dimethacrylate. When hydrated the lens consists of 45.0% HEMA and 55.0% water by weight of saline immersed in normal saline. The lens is visibility tinted aqua with: Reactive Blue No. 4 and Reactive Yellow Dye # 86. A benzophenone UV absorbing monomer is used to block UV radiation.

The average transmittance characteristics are less than 10% in the UVB range of 280 to 315nm and less than 40% in the UVA range of 315-380nm.

The SAUFLON 55 UV Contact Lens is a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Chord Diameter: 14.0mm to 15.0mm
- Centre Thickness: 0.03mm to 0.40mm
- Base Curve: 8.40mm to 9.30mm
- Powers: -20.00 Diopters to +20.00Diopters

The physical/optical properties of the lens are:

- Refractive Index: 1.40
- %Transmittance @ 590nm 94.61
- % Transmittance @ 280-315nm 9.41
- % Transmittance @ 316-380nm 36.00
- Surface Character: Hydrophilic
- Water Content: 55%
- Specific Gravity 1.09
- Oxygen Permeability (Dk): 22.0×10^{-11} (cm^2 / sec) (ml O_2 / ml x mm Hg) at 35°C
  (Fatt Method for determination of oxygen permeability)

COMPARISON OF PHYSICAL / OPTICAL PROPERTIES

PARAMETER	SAUFLON 55UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear	FREQUENCY 55 Hydrophilic Contact Lens for Daily Wear (clear and tinted)
Material	Methafilcon A	Methafilcon A
Indication for Use	Myopia, Hyperopia and Astigmatism	Myopia, Hyperopia and Astigmatism
Water Content	55%	55%
% Transmittance @590nm %Transmittance @280–315nm % Transmittance @316–380nm	94.61% 9.41% 36.00%	95.47% 82.47% 95.30%
DK @35°C (Edge Corrected)	22.0×10^{-11}	15.50×10^{-11}
Powers	-20.00 to +20.00 D	-20.00 to +20.00 D
Colour	Aquamarine Visibility	Clear and Aqua Visibility
Refractive Index	1.4020	1.4052
Tensile Strength	1.47	0.66
Modulus	0.52	0.48
Elongation at Break	280	179
Toughness	1.39	0.38
Manufacturing Method	Cast Moulding	Cast Moulding

PRECLINICAL TESTING

The results of toxicology testing (cytotoxicity, acute systemic toxicity and acute ocular irritation) show the lenses to be non-toxic and non-irritating. Furthermore, the results of residual monomer and colour leachability testing demonstrate that the respective extracts did not contain significant levels of leachable colour or residual monomers.

The physical optical, and chemical properties of the Sauflon 55 UV (methafilcon A) Soft Hydrophilic Visibility Tinted Contact Lens for Daily Wear are equivalent to those of the FREQUENCY 55 (methafilcon A) Hydrophilic Contact lenses for Daily Wear (clear and tinted). This lens is in group 4, Ionic, high water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994.

The lens will be sterilised and packaged in the same manner as previously cleared in K973063. This lens will also be sterility released by parametric release, as cleared in K971164.

INDICATIONS FOR USE

The Sauflon 55 UV (methafilcon) Soft (Hydrophilic) Visibility Tinted Contact Lens is indicated for daily wear for the correction of the refractive ametropia (myopia and hyperopia) and astigmatism in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Dioptres that does not interfere with visual acuity.

Eyecare practitioners may prescribe the lens for daily wear in Frequent Replacement Program. The lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

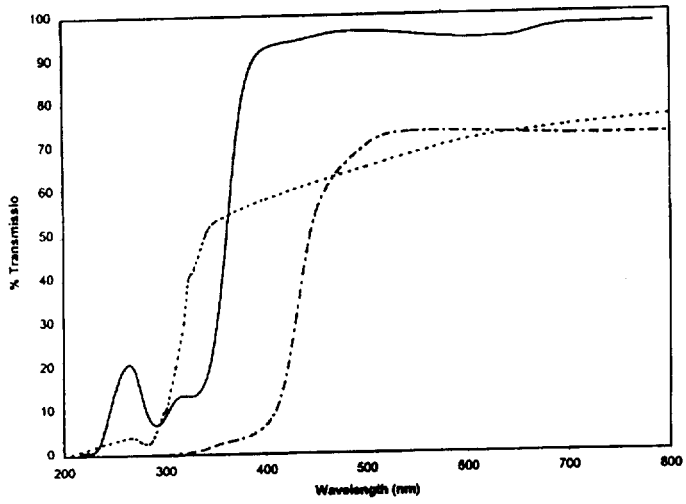
PARAMETERS AVAILABLE:

Sauflon 55 UV Contact Lens

Powers:	+8.00 to –10.00 D
Centre Thickness:	0.07mm
Diameter:	14.2mm
Base Curve:	8.6, 8.9mm (minus lenses) and 8.8mm (plus lenses)

Transmittance Curves

The figure below shows transmittance curves comparing the Sauflon 55UV (Methafilcon A with UV Blocker) contact lens with visibility tint and UV blocker, against those for a 24 yr. old human cornea and 25 yr. old human crystalline lens.



Key:

———— Sauflon 55UV (Methafilcon A with UV blocker) soft contact lens with visibility tint and UV blocker. Curve shown is for a –6.75D lens with a centre thickness 0.060 mm, which represents the transmittance characteristics of the thinnest version of this UV-absorbing lens to be marketed.

..... 24 Year old human cornea *1

-.-.-.-.- 25 year old crystalline lens *2

N.B

1 Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, fig2-21

2 Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 10, fig. 5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 6 2001

Dr. Ligia Delacruz
Sauflon Pharmaceuticals Ltd.
49-53 York Street
Twickenham, Middlesex
United Kingdom

Re: K013649
Trade/Device Name: SAUFLON 55 UV (methafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: SOFT (HYDROPHILIC) CONTACT LENS
Regulatory Class: II
Product Code: LPL
Dated: October 31, 2001
Received: November 5, 2001

Dear Dr. Delacruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SAUFLON PHARMACEL LIMITED

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013649

Device Name: Sauflon 55 UV (methafilcon A) soft (hydrophilic) visibility tinted contact lens for Daily Wear

Indications For Use: The Sauflon 55 UV soft (hydrophilic) contact lens is indicated for daily wear for the correction of the refractive ametropia (myopia and hyperopia) and astigmatism in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Dioptres that does not interfere with visual acuity.

Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using chemical or hydrogen peroxide disinfection systems.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-The Counter _____

Daniel G. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

510(k) Number K013649